Some media reports and health group websites have stated that the American Academy of Pediatrics (AAP) recommends that adolescents should not consume more than 100 mg of caffeine per day. However, following a thorough search of the literature a detailed reference for this statement could not be found in these reports.

In the FDA letter dated November 21, 2012 (U.S. FDA, 2012c), it is stated that the FDA contacted the AAP and reviewed their website but was not able to get verification that the AAP has a policy statement supporting an upper limit of 100 mg caffeine per day for adolescents.

We also did an independent search of the AAP website and did not identify any such policy statement. While no policy statement by the AAP was identified, an independent publication in the AAP journal Pediatrics by authors from the Department of Pediatrics and the Pediatric Integrative Medicine Program, University of Miami, Leonard M. Miller School of Medicine, Miami, Florida, Seifert *et al.* (2011), did state that "Adolescent and child caffeine consumption should not exceed 100 mg per day and 2.5 mg per kg BW per day, respectively", with three references provided as support for this intake limit. However, upon close review of the references, none laid out or were proven to recommend this intake limit. The references are summarized below:

1) Babu KM, Church RJ, Lewander W. Energy drinks: the new eye-opener for adolescents. Clin Pediatr Emerg Med. 2008;9(1):35–42. Babu *et al.* (2008) cites to Canadian recommendations that children aged 10 to 12 consume no more than 85 mg per day. No recommendations are given for adolescents aged 12 to 18.

2) BfR Federal Institute for Risk Assessment. Health risks of excessive energy shot intake. December 2, 2009. Available at: www.bfr.bund.de/cm/245/health_risks_of_excessive_energy_shot_intake.pdf. Accessed January 17, 2011. The BfR Federal Institute for Risk Assessment refers to "children" and uses a 10-year-old as an example but makes no reference to "teens" or "adolescents" or a 100 mg per day recommended limit. This reference focuses on energy shots and not energy drinks such as Rockstar. With respect to children, this article states the following: "With portions of 150 mg, children (10 years old, 30 kg BW) reach intake levels of 5 mg caffeine per kg BW. These have been connected with the temporary appearance of arousal, irritability, nervousness and anxiety in several children (SCF, 1999). These products should therefore be labelled as unsuitable for children."

   Interestingly, the SCF (1999) report which is cited by the BfR includes this statement: "Studies on the effects of direct caffeine consumption by pre-school and school children have given variable results. In experimental studies in which single doses up to 10 mg per kg bw have been given to children, either no effect or small, inconsistent effects have been noted on mood, behavioural, cognitive and motor functions, some of which could be interpreted as beneficial."

3) Heatherley SV, Hancock KM, Rogers PJ. Psychostimulant and other effects of caffeine in 9- to 11-year-old children. J Child Psychol Psychiatry. 2006;47(2):135–142. Heatherley *et al.* (2006) did not evaluate children older than 12 years of age.

Overall, the published literature collected that specifically looked at adolescent populations did not indicate that 100 mg per day of caffeine was likely to be associated with health concerns. In caffeine sensitive individuals, the effects of caffeine may be associated with transient behavioural changes, such as increased arousal, irritability, nervousness or anxiety (SCF, 1999). These are the same effects noted in sensitive adults and would be expected to be self limiting.

A recent letter prepared by the FDA (2012c) noted the following key points with respect to intakes of caffeine among consumers, including adolescents.

- Based on the results of a commissioned consumption study, the mean caffeine consumption by the U.S. population has remained stable, despite the entry of energy drinks on the market, at approximately 300 mg per person per day.
- Among consumers aged 14 to 21 years of age, the mean amount of caffeine consumed was 1/3 of that of adults or ~100 mg per day, with the caffeine contributed predominantly from coffee, soft drinks and teas.
- Caffeine intakes from energy drinks represented only a small portion of daily intakes, even for teens.

In related information, a recent media report ("Moderation key to energy drinks" Hinton Parklander, Mon Dec 3 2012, Byline: ED MOORE EDSON LEADER) cited the Alberta Health Services medical officer of health, Kathryn Koliaska, that older children (>12 years of age) should limit their intake of caffeine to 400 mg per day.

The U.S. National Center for Health Statistics' (NCHS) National Health and Nutrition Examination Surveys (NHANES) most recent data also suggest very low energy drink consumption among adolescents (CDC 2011). The NHANES data are collected and released in 2-year cycles with the most recent cycle containing data collected in 2009-2010. NHANES 2009-2010 survey data were collected from individuals and households *via* 24-hour dietary recalls administered on 2 non-consecutive days (Day 1 and Day 2). Additionally, NHANES respondents provided 24-hour recall data concerning the use of dietary supplements on 2 non-consecutive days.

The results as presented in Table 4 indicate that only 1.1% of adolescent girls and 4.5% of adolescent boys are consumers of energy drinks.

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Table 4	Summary of Most Relevant Dietary Intake Assessments Conducted Using 2009-2010 NHANES Data									
Population Group	Age Group (years)	Caffeine intakes from background diet[a], Caffeine Users[b] Only (mg/day)			Caffeine intakes from intended uses in energy drinks (120mg/8oz), Energy Drink Users Only (mg/day)			Caffeine intakes from background diet and intended uses in energy drinks (120mg/8oz), Energy Drink Users Only (mg/day)		
		% Users	n	Mean	% Users	n	Mean	% Users	n	Mean
Infants	0 to 2	42.2	648	8	0	0	na	0	0	na
Children	3 to 11	86.1	2,308	18	0.4	8	109*	0.4	8	121*
Female Teenagers	12 to 19	89.2	851	53	1.1	15	143*	1.1	15	172*
Male Teenagers	12 to 19	86.8	908	67	4.5	36	145	4.5	36	164
Female Adults	20 and up	94.1	4,757	155	1.8	65	105	1.8	65	156
Male Adults	20 and up	94.1	4,340	205	3.3	145	140	3.3	145	207
Total Population	All Ages	90.2	13,812	143	2.2	269	129	2.2	269	145

na=not applicable
[a] Background diet includes food and dietary supplements.
[b] A caffeine user is defined as a consumer of a caffeine-containing food and/or dietary supplement.
*low numbers of users diminishes reliability of results

Similarly in Canada, very low consumption estimates have been determined from surveys of adolescents (12 to 17 year olds) in the province of Quebec. The Réseau du sport étudiant du Quebec (RSEQ, 2011) surveyed the energy drink consumption habits of over 10,000 Quebec teens (12 to 17 years of age) and found that 93% of teens rarely or never consumed energy drinks while only 1% consumed them daily. Research by the Institut de la Statistique du Québec (Institut de la Statistique du Québec, 2012) in a survey of more than 60,000 teens (13 to 17 years of age) found that 82.8% of teens rarely or never consumed energy drinks, and only 1.5% consumed them daily. Based on information from Statistics Canada (2009), similar beverage consumption patterns occur all across Canada.

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6.0 OTHER INGREDIENTS

There are no safety concerns related to the other ingredients in Rockstar energy drink products, all of which are common in the diet.

As noted in the DAWN Report (SAMHSA, 2011), other ingredients in energy drinks may include vitamins, amino acids, herbs, sugars, and sugar alternatives. The specific ingredients in Rockstar are similar in nature and all are either GRAS ingredients or approved food additives.

The Expert Panel convened to undertake a safety evaluation of caffeine also assessed other ingredients in the Rockstar drinks including L-carnitine, and taurine, and the flavors ginseng extract, guarana extract, and milk thistle extract. The Expert Panel concluded that under the conditions of intended use in Rockstar energy drink products, these ingredients are safe and GRAS based on scientific procedures.

L-Carnitine is a naturally occurring compound found in all mammalian species. It is required for conversion of fatty acyl coenzyme A (CoA) esters for energy. L-Carnitine is produced endogenously by humans, and occurs naturally in the diet as a component of meat and dairy products, and found in negligible amounts in fruits and vegetables. The safety of L-carnitine also is corroborated by the findings of numerous human studies conducted on L-carnitine that included endpoints relevant to safety. In these studies, no adverse effects attributable to the consumption of L-carnitine were reported following daily oral ingestion at doses ranging from 2 to 3 g L-carnitine per day for up to 3 months and at a dose of 2 g per day for up to 6 months. L-Carnitine is also acceptable for use in baby foods and infant formula (EFSA, 2003).

***Panax* Ginseng Extract**: The safety of *P.* ginseng extract is corroborated by the findings of numerous human studies in which *P. ginseng, P. ginseng* rootlets, body, and extracts (aqueous or ethanolic), *P. quinquefolius* root, *P. notoginseng* root, panaxtriol saponin from *Radix/Rhizoma notoginseng* extract, *P. japonicas* root, and *P. vietnemensis* root were consumed by generally healthy subjects or those with various underlying diseases or conditions. Although the various species may differ quantitatively in ginsenoside content, qualitatively, many of the ginsenosides are common to all of the species. Thus, the human studies conducted with various ginseng species also are directly relevant to the safety of the *P. ginseng* extract intended for use in Rockstar energy drink products. The overall absence of treatment-related differences in any of the safety-related parameters assessed following the consumption of up to 9 g per day *P. ginseng* or up to 2 g per day *P. ginseng* extracts for periods of up to 24 weeks further supports the safety of the intended use of *P. ginseng* extract in energy drinks.

Guarana Extract: Guarana extract is an approved food additive permitted for use as a natural flavoring substance and natural substance used in conjunction with flavors (21 CFR 172.510). Guarana also is considered to be Generally Recognized as Safe (GRAS) for use as a flavoring

agent by the Flavor and Extract Manufacturers' Association of the United States. Of the ingredients in Rockstar energy drink products, only the guarana seed extract contains some minor amounts of caffeine. The maximum guarana seed extract present in each 8 oz. serving of Rockstar energy drink products would contribute less than 1 mg of caffeine, which is insignificant in comparison to the 80 mg or 120 mg of caffeine added directly to the drink.

Milk thistle extract: As a food, several parts of the milk thistle plant are consumed, including the flowers (seeds), leaves, heads, and roots. In Canada, the NHP monograph for milk thistle extract considers intakes of 140 mg to 600 mg per day silymarin (calculated as silybin/silibinin), not to exceed 200 mg per dose, safe for consumption (Health Canada, 2009). In the monograph published by the German Commission E, 200 mg to 400 mg per day silymarin (calculated as silibinin) are considered safe (Blumenthal *et al.*, 1998). The lowest of these intakes (*i.e.,* 140 mg per day silymarin), is 41-fold greater than the estimated 90th percentile intake of silymarin in energy drink users from all sources (*i.e.,* from the intended use of milk thistle extract in energy drinks plus the intake of milk thistle from dietary supplements).

Taurine occurs naturally in the diet as a component of meat and poultry, seafood, and dairy products. It also is present in breast milk and infant formula (4 mg to 7 mg per 100 mL) (Laidlaw *et al.*, 1990; Hayes and Trautwein, 1994). The presence of taurine in cow's milk-based infant formula is attributed to its natural occurrence in the milk, whereas taurine is added to infant formula formulated from soy protein (Laidlaw *et al.*, 1990). Infants cannot produce taurine and require it from breast milk or formula, therefore taurine is a conditionally essential amino acid. Safety is corroborated by the findings of numerous human studies conducted on taurine that included endpoints relevant to safety. In these studies, no adverse effects attributable to the consumption of taurine were reported. The European Food Safety Authority (EFSA) reviewed the available human data and concluded that daily oral ingestion of taurine at doses ranging from 3 g to 6 g per day for up to 1 year did not produce adverse health effects (EFSA, 2009). More recently, EFSA's Panel on Additives and Products or Substances used in Animal Feed estimated the observed safe level of taurine in humans to be 6 g per person per day (EFSA, 2012).

It should also be noted that taurine does not have any stimulatory activity. Thus, there is no potential enhanced activity of caffeine due to the presence of taurine. L-Carnitine which is a derivative of the amino acid lysine is not a stimulant and therefore does not compound caffeine activity.

Estimates of exposure to these non-caffeine ingredients from consumption of energy drinks were determined to be well below estimates of consumption from other food sources and/or orders of magnitude below no-adverse-effect levels determined from safety studies. As confirmed by the independent Panel of food safety experts, the above described ingredients, there is no expected

safety concern associated with these ingredients alone, or in combination, from consumption of Rockstar energy drink products.

7.0 CONCLUSIONS

There is insufficient information presented in the CAERS summaries (through October 2012) or the DAWN report to demonstrate that energy drinks were the cause of the adverse events noted therein. Furthermore, there are no data to indicate that Rockstar energy drinks containing 80 mg or 120 mg per 8 oz. serving, caused any adverse events. Some of the other brand energy drinks on the market have more than twice this amount of caffeine per ounce. The amount of caffeine in various coffees is higher than the same volume of Rockstar energy drink products. Concentrations of caffeine present in 16 oz. servings of Einstein Bros. and Starbucks coffee were 300 mg and 320 mg, respectively. The 20 oz. serving of Starbucks Pike Place Roast contains 415 mg of caffeine. Thus, 8 oz. servings of Starbucks or Einstein Bros. coffees would provide more caffeine (160 and 150 mg, respectively) than would be provided in an 8 oz. serving of Rockstar products (80mg or 120 mg). Ben and Jerry's Coffee Heath Bar Crunch also contains 84 mg of caffeine per 8 oz. serving.

Rockstar, Inc. has produced over 3 billion cans of Rockstar energy drink products in the USA since brand inception in 2001 and approximately 2 billion cans since 2006. The incidence of alleged adverse events reports in CAERS (through October 2012) citing Rockstar products is incredibly low at 13 total, or 0.00000065%, compared to 2 billion cans sold during the timeframe (through October 2012) that the CAERS reports were received. There has never been an incidence of a reported death from consumption of a Rockstar energy drink product. Current annual energy drink consumption in the USA, total category, is estimated at 4.4 billion units. The number of hospital visits listing energy drinks with and without alcohol and drug substances as reported by SAMHSA in 2011 was 20,783. These events are taken from hospital charts at emergency rooms and they do not appear to be substantiated for legitimacy (*i.e.*, reports are anecdotal and appear not to have been medically vetted). The incidence of visits in 2011 compared to the annual energy drink consumption at that time total category, estimated at 3.5 billion units, would be approximately 0.000006% or 1 visit for every 168,400 units sold. Excluding the visits where there was admission of alcohol and drug combination use, the incidence would about 0.0000034% or 1 visit for 290,360 units sold.

Any substance if administered at high enough doses may be fatal. The amount of caffeine that is reported in the literature to be fatal to adults is approximately 10,000 mg. Therefore, an adult would need to consume 83 cans of 8-oz. (at 120 mg caffeine) Rockstar energy drink products to reach fatal caffeine levels. The total volume of fluid required to be consumed to reach these levels is 664 oz. (43 pounds of fluid) or about 20 L, which is 10 times the typical amount of total fluid consumed in a full day by an adult.

It is acknowledged that there are certain populations that are potentially sensitive to caffeine. However, all Rockstar energy drink product labels recommend against consumption of energy drinks by children, pregnant or nursing women, or those sensitive to caffeine.

The safety of the amount of caffeine used in Rockstar energy drink products (up to 120 mg per 8 oz. serving) is supported by the findings of an Expert Panel convened to evaluate the conditions of use of caffeine in Rockstar products. The Expert Panel unanimously concluded that the intended use of caffeine, produced in accordance with current good manufacturing practice and meeting applicable *Food Chemical Codex* specification, in Rockstar energy drink products at levels **up to 120 mg per 8 oz. serving** is both safe and generally recognized as safe (GRAS) based on scientific procedures.

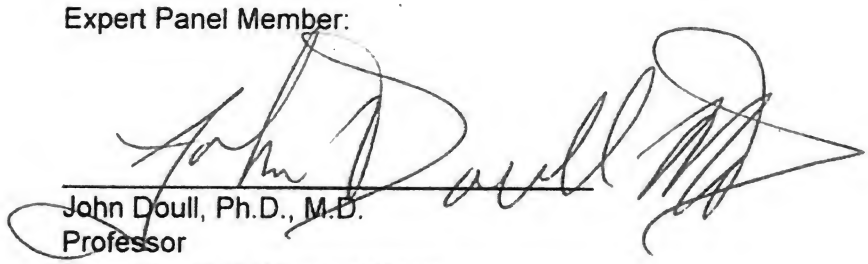
The FDA (2012b) has stated in a letter dated August 10, 2012, that, while the Agency is reviewing recently published safety studies on caffeine, the available studies do not indicate any new, previously unknown risks associated with caffeine consumption.

Given the above, there is no expectation that consumption of Rockstar energy drink products containing 80 mg or 120 mg caffeine per 8 oz. serving, in adherence with the product label, should be associated with adverse health effects.

Also, the Expert Panel convened to assessment caffeine also assessed *Panax* ginseng extract, guarana extract, L-carnitine, inositol, milk thistle extract, and taurine, and concluded that under the conditions of intended use, including use levels and estimated dietary intakes, in Rockstar energy drink products, these ingredients are both safe, and GRAS, based on scientific procedures. The guarana extract ingredient does not significantly increase caffeine amounts. The caffeine content of the guarana seed extract is 0.75 to 1.25%; provides an additional 0.0875 mg which is insignificant compared to the 80 mg or 120 mg of caffeine added directly to an 8 oz. serving). Estimates of exposure to these non-caffeine ingredients from consumption of Rockstar energy drink products were determined to be well below estimates of consumption from other food sources and/or orders of magnitude below no-adverse-effect levels determined from safety studies. Thus, there is no expected safety concern associated with these ingredients alone, or in combination, from consumption of Rockstar energy drink products.

Furthermore, scientific research that has compared caffeine consumer to non-consumers, has found that the consumption of caffeine enhances mental and physical performance (Smith, 2002; Ruxton, 2008).

Expert Panel Member:



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CFR Sections Referenced (Title 21—Food and Drugs)		
Part	Section §	Section Title
170—Food additives	170.3	Definitions
	170.30	Eligibility for classification as generally recognized as safe (GRAS)
172—Food additives permitted for direct addition to food for human consumption	172.510	Natural flavoring substances and natural substances used in conjunction with flavors
340—Stimulant drug products for over-the-counter human use	All sections	All sections

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